



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/891,691	06/26/2001	John Bondo Hansen	6034.200-US	1796

7590 05/20/2003

Reza Green, Esq.
Novo Nordisk of North America, Inc.
Suite 6400
405 Lexington Avenue
New York, NY 10174-6401

EXAMINER

JIANG, SHAOJIA A

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 05/20/2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n N .

09/891,691

Applicant(s)

HANSEN ET AL.

Examiner

Shaojia A. Jiang

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on February 24, 2003 and January 13, 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) 13-18 and 25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-12, 19-24, 26 and 27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 24, 2003 has been entered in Paper No. 14.

This Office Action is a response to Applicant's request for continued examination (RCE) filed February 24, 2003 in Paper No. 14, and amendment and response to the Final Office Action (mailed August 13, 2002), filed January 13, 2003 in Paper No. 10 wherein claim 2 has been amended. Currently, claims 1-27 are pending in this application.

Claims 13-18 and 25 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected species. See the previous Office Action dated January 15, 2002.

The claims have been examined insofar as they read on the elected specie.

Claims 1-12, 19-24, and 26-27 are examined on the merits herein.

Applicant's amendment filed on January 13, 2003 in Paper No. 10 with respect to the rejection of claim 2 made under 35 U.S.C. 112 second paragraph for the use of the indefinite expressions, i.e., "from about 10 kcal% fat" of record stated in the Office

Art Unit: 1617

Action dated August 13, 2002 have been fully considered and found persuasive to remove the rejection since the indefinite expression has been deleted from the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-12, 19-24, and 26-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nielsen et al. (US 5889002, WO 9726265, and WO 9903861, of record) in view of the Merck Manual of Diagnosis and Therapy (17th ED) (see pages 59-61, PTO-892).

Nielsen et al. (US 5889002) discloses that the active compounds represented by the general formula I therein which has covered the instant elected species (see abstract, col.1 lines 21-22, 45-50, col.2 lines 29 to col.7) are potassium channel openers and useful in a method of treating various diseases of the central nervous system and the cardiovascular system broadly, e.g., hypertension, heart diseases, coronary heart diseases (see col.13 lines 19-24), and especially in methods of treating obesity hyperinsulinemia, insulin resistance and diabetes (see col.13 line 62 to col.14 lines 8). Nielsen et al. further discloses that the range of effective amounts of active compounds therein to be administered is within the instant range. See col. 18 lines 53-55.

Nielsen et al. (WO 9726265) discloses that the active compounds represented by the general formula I therein which has covered the instant elected species are potassium channel openers and useful in a method of treating various diseases of the central nervous system and the cardiovascular system broadly, e.g., hypertension, heart diseases (see abstract, page 1 lines 11, 16, 26-27, and 32-33, page 3-10 and page 52 claim 25) and especially in methods of treating obesity hyperinsulinemia, insulin resistance and diabetes (see page 20 lines 9-16). Nielsen et al. further discloses that the range of effective amounts of active compounds therein to be administered is within the instant range. See page 27 lines 18-20.

Nielsen et al. (WO 9903861) discloses that the active compounds represented by the general formula I therein which has covered the instant elected species are potassium channel openers and useful in a method of treating various diseases of the central nervous system and the cardiovascular system broadly, e.g., hypertension, heart disease (see abstract, page 1 lines 8, 26 and 32-33, page 3-13 and page 52 claim 25) and especially in methods of treating obesity hyperinsulinemia, insulin resistance and diabetes (see page 20 lines 10-18).. Nielsen et al. also teaches that potassium channel openers are also known to be useful in the treatment of obesity and decreasing weight gain. See page 2 lines 30 to page 3 line 3. Nielsen et al. further discloses that the range of effective amounts of active compounds therein to be administered is within the instant range. See page 30 lines 4-6.

Nielsen et al. does not expressly disclose a method for reducing the consumption of fat-containing food employing the active compounds of Nielsen et al., represented by

Art Unit: 1617

the general formula I therein. Nielsen et al. does not expressly disclose the instant fat-containing food contains at least 10 kcal% fat.

The Merck Manual of Diagnosis and Therapy (16th ED) teaches that that a large amount of fat-containing food to be consumed or a large fat intake is tightly associated with obesity (see 4th paragraph of the right column at page 59), and the complications of obesity are known to be hypertension, hyperinsulinemia, diabetes and coronary heart disease. See the right column of page 61.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ the active compounds of Nielsen et al., represented by the general formula I therein, in a method for reducing the consumption of fat-containing food, and to employ food herein containing from 10-45 kcal% fat.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ the active compounds of Nielsen et al., represented by the general formula I therein, in a method for reducing the consumption of fat-containing food since the active compounds of Nielsen, potassium channel openers, are known to be useful in methods of treating hypertension, heart disease, and especially obesity hyperinsulinemia, insulin resistance and diabetes. Moreover, a large amount of fat-containing food to be consumed or a large fat intake is well known to be tightly associated with obesity, and the complications of obesity are known to be hypertension, hyperinsulinemia, diabetes and coronary heart disease according to Merck Manual. Therefore, one of ordinary skill in the art would have reasonably expected that the active compounds of Nielsen would have beneficially therapeutic effect in treating

Art Unit: 1617

obesity and its complications by reducing the consumption of fat-containing food which may contain at least 10 kcal% fat.

Hence, the disclosures of Nielsen et al. have clearly provided the motivation for the instant invention. Thus the claimed invention as a whole is clearly prima facie obvious over the combined teachings of the prior art.

Applicant's remarks filed January 13, 2003 in Paper No. 10 with respect to this rejection of claims 1-12, 19-24, and 26-27 made under 35 U.S.C. 103(a) of record stated in the Office Action dated August 13, 2002 have been fully considered but are not deemed persuasive as to the nonobviousness of the claimed invention over the prior art. These remarks are believed to be adequately addressed by the obvious rejection presented above.

As discussed in the previous Office Action August 13, 2002, it is noted that Applicant admits herein that obesity is tightly associated with the amount of fat-containing food to be consumed or fat intake since Applicant employs an obese Zucker rat as the testing model for the instant claimed method. See page 23 lines 1-15 in the specification. Thus, Applicant clearly acknowledges that obesity is tightly associated with the amount of fat-containing food to be consumed or fat intake as discussed by the examiner above. Therefore, Applicant's own admission supports the examiner's position for the motivation for the instant invention.

Applicant's testing results in the specification at page 23 lines 1-15 have been fully considered with respect to the nonobviousness and/or unexpected results of the claimed invention but are not deemed persuasive since the results on the employment

Art Unit: 1617

of the particular compound on obese rates show expected therapeutic effects as taught and suggested by the cited prior art herein. Therefore, the results herein are clearly expected and not unexpected based on the cited prior art. Expected beneficial results are evidence of obviousness. See MPEP § 716.02(c). Further, testing herein merely demonstrate a single particular compound within the broad genus of the instant claims. Thus, the evidence in the examples is also not commensurate in scope with the claimed invention and does not demonstrate criticality of a claimed range of the actives in the claimed method herein. See MPEP § 716.02(d).

Therefore, the evidence presented in specification herein is not seen to support the nonobviousness of the instant claimed invention over the prior art.

For the above stated reasons, said claims are properly rejected under 35 U.S.C. 103(a). Therefore, said rejection is adhered to.

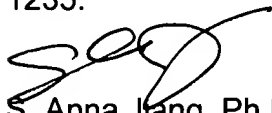
In view of the rejections to the pending claims set forth above, no claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (703) 305-1008. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Art Unit: 1617

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

A handwritten signature in black ink, appearing to read 'S. Anna Jiang', is positioned above the printed name.

S. Anna Jiang, Ph.D.
Patent Examiner, AU 1617
May 7, 2003